Notice of Allowability	Application No.	Applicant(s)	
	09/840,669	KOHNO, TADAHIKO	
	Examiner	Art Unit	
	Chih-Min Kam	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *10/15/03*.
2. ☒ The allowed claim(s) is/are *1-4,6-9 and 11-13*.
3. ☒ The drawings filed on *23 April 2001* are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
   (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No. ____.
   (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
   (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1☐ Notice of References Cited (PTO-892)
2☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____
4☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5☐ Notice of Informal Patent Application (PTO-152)
6☒ Interview Summary (PTO-413), Paper No. *0104* .
7☒ Examiner's Amendment/Comment
8☐ Examiner's Statement of Reasons for Allowance
9☐ Other .

An **Examiner's Amendment** to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Timothy Gaul on January 14, 2004.

Examiner's Amendments to the Specification:

Please replace the original Abstract with the following Abstract.

Abstract

The present invention concerns therapeutic agents that mimic the activity of Apo-AI amphipathic helix peptide. In accordance with the present invention, the compounds of the invention comprise:

a. a Apo-AI amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domain, preferably the amino acid sequence of SEQ ID NO: 7, or sequences derived therefrom by phage display, RNA-peptide screening, or the other techniques mentioned above; and

b. a vehicle, such as a polymer (e.g., PEG or dextran) or an Fc domain, which is preferred;

wherein the vehicle, preferably an Fc domain, is covalently attached to the Apo-AI amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domain. The vehicle and the Apo-AI amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domain may be linked through the N- or C-terminus of the Apo-AI amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domain, as described further below. The preferred vehicle is an Fc domain, and the preferred Fc domain is an IgG Fc domain. Preferred Apo-AI amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domains comprise the amino acid

sequences described in Table 2. Other Apo-AI amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domains can be generated by phage display, RNA-peptide screening and the other techniques mentioned herein.

Please replace the first paragraph after "Brief Description of the Figures" at page 5 with the following paragraph:

[Figure 1] Figures 1A-1F show[s] exemplary Fc dimers that may be derived from an IgG1 antibody. "Fc" in the figure represents any of the Fc variants within the meaning of "Fc domain" herein. "X^1" and "X^2" represent peptides or linker-peptide combinations as defined hereinafter. The specific dimers are as follows:

Please replace the paragraph at lines 17-26 of page 6 with the following paragraph:

[Figure 2] Figures 2A-2C show[s] the structure of preferred compounds of the invention that feature tandem repeats of the pharmacologically active peptide. Figure 2A shows a single chain molecule and may also represent the DNA construct for the molecule. Figure 2B shows a dimer in which the linker-peptide portion is present on only one chain of the dimer. Figure 2C shows a dimer having the peptide portion on both chains. The dimer of Figure 2C will form spontaneously in certain host cells upon expression of a DNA construct encoding the single chain shown in Figure 3A. In other host cells, the cells could be placed in conditions favoring formation of dimers or the dimers can be formed in vitro.

Please replace the paragraph at lines 27-29 of page 6 with the following paragraph:

[Figure 3] Figures 3A and 3B show[s] exemplary nucleic acid and amino acid sequences (SEQ ID NOS:1 and 2, respectively) of human IgG1 Fc that may be used in this invention.

Examiner's Amendments to the Claims:

Claim 1 has been amended as follows:

Claim 1 (currently amended): A composition of matter of the formula

$$(A^1)_a\text{-}F^1\text{-}(A^2)_b$$

and multimers thereof, wherein:

F^1 is an Fc domain of an antibody;

A^1 and A^2 are each independently selected from $-(L^1)_c\text{-}P^1$, $-(L^1)_c\text{-}P^1\text{-}(L^2)_d\text{-}P^2$, $-(L^1)_c\text{-}P^1\text{-}(L^2)_d\text{-}P^2\text{-}(L^3)_e\text{-}P^3$, and $-(L^1)_c\text{-}P^1\text{-}(L^2)_d\text{-}P^2\text{-}(L^3)_e\text{-}P^3\text{-}(L^4)_f\text{-}P^4$;

P^1, P^2, P^3, and P^4 are each independently sequences of apolipoprotein AI (Apo-AI) amphipathic helix peptide or Apo-AI amphipathic helix peptide -mimetic domains;

L^1, L^2, L^3, and L^4 are each independently linkers; and

a, b, c, d, e, and f are each independently 0 or 1, provided that at least one of a and b is 1.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. CMK
Patent Examiner

ROBERT A. WAX
PRIMARY EXAMINER

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January 14, 2004